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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,104	09/26/2003	Wan Ji	INV850/4-001CON/58001	7870

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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/672,104

Applicant(s)

JI ET AL.

Examiner

Kenneth R. Horlick

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 71-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. In light of the preliminary amendment filed 09/26/05 which crossed in the mail with the Office action mailed 09/29/05, said Office action is hereby WITHDRAWN in favor of this new Office action.
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The specification is objected to because of the following informality: the continuation information must be updated to reflect issue of the parent '565 application as U.S. Patent No. 6,638,722.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71-84, 89, and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohlander (US 5,731,171).

These claims are drawn to a composition comprising: a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase.

Bohlander discloses a kit comprising such a first and second primer along with such a polymerase (see columns 3-9 and 13-14, especially column 8, line 18 to column 9, line 24). This kit may be reasonably interpreted as a "composition" as claimed.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 85-88 and 91-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohlander.

While the exact compositions of these claims are not disclosed in the cited patent, the further limitations relate merely to additional conventional polymerases, labels, primer sites, and target nucleic acids. As these represent mere textbook knowledge, one of ordinary skill in the art would have been motivated to use them in the method and kit of Bohlander for their well known and obvious benefits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed compositions.

6. Claims 71-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheleznaya et al. in view of Bohlander.

Zheleznaya et al. teach a method which utilizes: a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase (see pages 373-377).

This publication does not disclose the claimed composition.

Kits or compositions combining reagents for facilitating the practice of methods requiring such reagents were conventional in the art at the time of the invention. This is supported by Bohlander, which as discussed above discloses kits.

One of ordinary skill in the art would have been motivated to combine the first and second primers and heat-stable polymerase of Zheleznaya et al. into a composition or kit because this would have clearly been useful in carrying out the method of Zheleznaya et al. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed compositions.

7. Claims 71-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grothues et al. in view of Bohlander.

Grothues et al. teach a method which utilizes: a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase (see pages 1321-1322).

This publication does not disclose the claimed composition.

Kits or compositions combining reagents for facilitating the practice of methods requiring such reagents were conventional in the art at the time of the invention. This is supported by Bohlander, which as discussed above discloses kits.

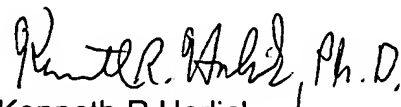
One of ordinary skill in the art would have been motivated to combine the first and second primers and heat-stable polymerase of Grothues et al. into a composition or kit because this would have clearly been useful in carrying out the method of Grothues et al. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed compositions.

8. No claims are free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

12/27/05